

## **REMARKS**

This Response Under 37 CFR §1.116 is respectfully submitted in response to the Final Rejection rendered October 23, 2006. A Request for Continued Examination is respectfully filed concurrently herewith to maintain pendency of this application.

Claim 77 has been amended to clarify that it refers to a soybean extract comprising serine protease activity. Claim 78 has been amended to change “soybean milk” to –soybean extract—so as to clarify the language of the claims. Support for these amendments is located in the Specification in the original claims.

The Final Rejection of October 23, 2006 rejected claims 75-85 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully request reconsideration of this rejection in view of the amendments to the claims set forth above.

The Final Rejection of rejected claims 75-85 under 35 U.S.C. 102(a or b) as being anticipated by Collins, Motitschke et al., JP 408143442, CN 1081899, JP 04283518 or JP 410226642. Applicants respectfully request reconsideration of this rejection in view of the amendments to the claims and the ensuing discussion.

The Final Rejection gives, as basis for the rejection, that the “soybean extract of the references and that claimed are one and the same.” [Final Rejection, p. 3] Applicants respectfully submit that none of the cited references teaches or suggests the soybean extract of applicants’ claimed compositions and methods that has active trypsin inhibitory activity.

In general, applicants respectfully note that the reference to a “soy extract” in a cited patent or publication does not necessarily pinpoint the particular extracts that are useful in the compositions and methods of applicants’ invention. There are a variety of extracts obtained from the soy plant by different means, which do not necessarily suggest or disclose the soy extracts containing trypsin inhibitory activity of the compositions and methods of applicants’ invention.

Applicants have had the entire JP8143442 publication translated and have attached a copy of this translation hereto. JP8143442 relates to an “immersed solution”, i.e., water in which soybeans have been immersed for five minutes to 20 hours at a temperature from 5 to 100°C and from which the soybeans have been removed. It is unlikely that such a solution

will contain the active STI proteins—the STI protein is a 181-amino acid protein having two disulfide bridges. As this is a fairly large protein, those of ordinary skill in the art would not expect it to diffuse out of the soybean and into an aqueous medium without some physical action, e.g., by crushing or breaking the bean. Furthermore, because STI is heat sensitive, if it is exposed to temperatures up to 100°C (as suggested in JP8143442), it would be denatured. Therefore, even if the STI protein were present, it would be inactive and, therefore, would not have disclosed or suggested the compositions and methods of the current invention.

CN 1081899 relates to a Chinese ointment containing, *inter alia*, “pure soybean oil...” Soybean oil does *not* contain soy trypsin inhibitors, as proteins are known to be insoluble in hydrophobic media. Thus, CN 1081899 would not have taught or disclosed the soy extracts containing trypsin inhibitory activity of the compositions and methods of applicants’ invention.

Motitschke et al. relates to compositions for treatment of skin disorders using brewers’ grains extract, a material that has been processed to a high temperature (70 - 75°C), fermented, saccharified and subjected to enzymatic processing [Motitschke et al., col. 2, l. 20-38]. Such a process denatures the STI proteins in the soy extract: fermentation is a standard technique of the soy food industry to inactivate STI and enable digestion of soy products without harmful gastric effects. Thus, Motitschke neither suggests nor describes the soy extracts of applicants’ invention.

JP 04283518 relates to anti-periodontal disease agents containing genistein—such an extract does not contain STI proteins. Rather, the soybeans are soaked in pH 8-11 water, which would inactivate STI at 50-60°C, the extract is then hydrolysed and filtered to give a “fraction contg. isoflavones.” [JP 04283518] Such an extract would not contain fractions having STI activity. In its broadest sense, hydrolysis is a reaction between any substance and water; however, the use of the term is commonly restricted to those reactions due directly to the hydrogen and hydroxyl ions of the water. The products of protein hydrolysis are peptides and amino acids. Therefore, when a protein-containing extract is hydrolyzed the proteins are no longer intact and functional and, thus, would not contain STI activity.

JP410226642 relates to an oral product containing genistein, which must be denatured in order to be ingested by humans [See, e.g., Declaration of Miri Seiberg dated January 17, 2006, ¶¶4-6]. Collins also refers to “soybean oil” [Collins, col. 2, l. 21], which, as noted above, does not contain STI activity.

In view of the insufficiency of the cited references to teach or suggest the compositions or methods of their invention, Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 102 (a or b).

In view of the foregoing, applicants respectfully request reconsideration of the rejections set forth in the Final Rejection of October 23, 2006. An early allowance is earnestly solicited.

Respectfully submitted,

By: /Andrea L. Colby/  
Andrea L. Colby  
Attorney for Applicants  
Reg. No. 30,194

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2792  
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